UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

ROBERT GUSTAVSEN, JOSEPH CUGINI, DEMETRA COHEN, LEE WILBURN, JACKIE CORBIN, MARY LAW and CECELIA BRATHWAITE, on behalf of themselves and all others)	
similarly situated,	
Plaintiffs,)	Civil Action No. 1:14-cv-11961-MLW
v.	
ALCON LABORATORIES, INC.; ALCON RESEARCH, LTD.; FALCON PHARMACEUTICALS, LTD.; SANDOZ, INC.; ALLERGAN, INC.; ALLERGAN USA, INC.; ALLERGAN SALES, LLC; PFIZER INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; BAUSCH AND LOMB INCORPORATED, ATON PHARMA, INC.; MERCK & CO., INC.; MERCK, SHARP & DOHME CORP.; PRASCO, LLC; and AKORN, INC.,	
Defendants.	

STIPULATED PROTECTIVE ORDER OF CONFIDENTIALITY

WHEREAS, to facilitate the production and receipt of information during discovery in the above-captioned matter, the parties agree and stipulate, through their respective counsel, to the entry of the following Protective Order for the protection of Confidential Information (as defined herein) that may be produced or otherwise disclosed during the course of this litigation by or on behalf of any party or non-party,

NOW THEREFORE, the Court, for good cause shown, hereby ORDERS, as follows:

1. **Purpose.** The preparation for trial of this action may require the discovery of certain documents and testimony that a defendant reasonably and in good faith believes should

be subject to a protective order under Federal Rule of Civil Procedure 26(c)(1)(G) or other state or federal law, including but not limited to trade secrets, research, design, development, financial, technical, marketing, planning, personal, proprietary, or commercial information, as such terms are used in Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure and any applicable case law interpreting Rule 26(c)(1)(G) or the former Rule 26(c)(7). Such materials may include (a) documents in the New Drug Application ("NDA") files and any Supplemental, Amended, and Abbreviated NDAs for the products manufactured, distributed, and/or sold by Defendants that are the subject of this action; (b) documents and information made confidential pursuant to statute, law, or regulation of any jurisdiction; (c) all other documents and information that contain trade secrets, research, design, development, financial, technical, marketing, planning, personal, proprietary, or commercial information and that a defendant marks as "confidential," "highly confidential," or "highly confidential/outside attorneys' eyes only"; and (d) all material, data, and information obtained, derived, or generated from such materials. Such documents, testimony, and information are referred to below as "Confidential Information."

2. **Designation by Producing Party Defendant.**

(a) For purposes of this Order, the term "document" means all written, recorded, or graphic material as described and defined in Rule 1001(1) and (2) of the Federal Rules of Evidence and shall include electronically stored information. A defendant party producing documents or serving written discovery responses that such party defendant determines in good faith, after appropriate review by an attorney or by a person working under the supervision of an attorney, contain Confidential Information, shall designate such documents by placing a stamp or marking on the documents stating the following: **CONFIDENTIAL [or HIGHLY CONFIDENTIAL/ ATTORNEYS'**

EYES ONLY, or HIGHLY CONFIDENTIAL /OUTSIDE ATTORNEYS' EYES ONLY], SUBJECT TO PROTECTIVE ORDER, PRODUCED BY [PARTY NAME] IN CASE NO. 1:14-cv-11961-MLW (D. Mass.). Such markings will not obscure, alter, or interfere with the legibility of the original document. Documents so marked are referred to in this Order as "Protected Documents."

- (b) A defendant may designate as "CONFIDENTIAL" those documents and materials that constitute formulas, formulations, designs, technical or non-technical data, devices, methods, techniques, drawings, processes, research, development, manufacturing, financial data, pricing, or proprietary commercial or business information that (i) are sufficiently secret to derive economic value or economic advantage, actual or potential, from not being generally known to other persons who can obtain economic value from their disclosure or use, and (ii) are not generally known and would not normally be disclosed to third parties (or, if disclosed, would require such third parties to maintain the information on a confidential basis), and are the subject of efforts that are reasonable under the circumstances to maintain their secrecy or confidentiality. The materials designated as "CONFIDENTIAL" must be limited solely to the actual confidential information as defined herein, and shall not include other, non-confidential portions of documents that contain confidential information.
- (c) A defendant may designate as "HIGHLY CONFIDENTIAL/OUTSIDE ATTORNEYS' EYES ONLY" those materials that otherwise qualify as "CONFIDENTIAL," and, in addition, are of such a highly sensitive, secret, or proprietary nature that the designating defendant believes reasonably and in good faith that disclosure of the materials to persons other than those identified in paragraph 5(g) of this Order

would create a material risk of serious and irreparable injury to the designating defendant's commercial or business interests.

- (d) Portions of interrogatory answers, responses to requests for admissions, deposition transcripts and exhibits, pleadings, motions, affidavits, and briefs that quote, summarize, or contain Confidential Information shall be Protected Documents, but, to the extent feasible, shall be prepared in such a manner that the Confidential Information is bound separately from that not entitled to protection; these portions that quote, summarize, or contain materials entitled to protection will remain Protected Documents regardless of labeling.
- (e) Confidential Information disclosed by a third party shall be covered by this Order if a party notifies all other parties within thirty (30) days of receipt of such information that the information or portions thereof constitute or contain Confidential Information. Until the expiration of thirty (30) days following receipt of such information, the information disclosed by any such third party shall be treated as Confidential Information under this Order.
- (f) A producing party may not globally designate materials as Confidential Information.
- 3. **Depositions.** Protected Documents may be used or marked as exhibits in depositions but shall remain subject to this Order. If deposition testimony discloses Confidential Information, counsel for the deponent or any party shall inform the deposing counsel of the confidentiality of any such testimony not later than twenty (20) days after receiving a copy of the deposition transcript or by making the confidential designation as to the specific testimony in question on the record at the deposition to be separately marked by the court reporter. Until

expiration of the 20-day period, the entire deposition will be treated as a Protected Document under this Order. If no party or deponent timely designates Confidential Information in a deposition, then none of the transcript or its exhibits shall be treated as confidential or highly confidential. If a designation is made, all such testimony, each deposition transcript, recording, or portion thereof, and each exhibit that is so designated, shall be treated as Confidential Information unless otherwise agreed to by the parties or directed by order of the Court.

4. Non-Disclosure of Confidential Information.

- (a) Confidential Information shall not be disclosed in any way to anyone for any purpose other than as required for the preparation and trial of the above-captioned matter. Access to and disclosure of Confidential Information shall be limited to those persons designated as Qualified Persons below. All Qualified Persons given access to Confidential Information shall keep all such information confidential from all other persons except as specifically provided in this Order.
- (b) To avoid security risks currently inherent in certain current technologies and to facilitate compliance with the terms of this Order, including, without limitation, the provisions of paragraphs 6(c), 8, and 9, and unless the party whose confidential information is at issue agrees otherwise in writing, and except as set forth immediately below with respect to limited electronic mail communications, all Qualified Persons with access to Confidential Information shall be and are prohibited from storing any Confidential Information in any online or web-based storage location, when such storage location is managed or maintained by any third-party service provider, including any provider of so-called "cloud computing" services, other than a reputable litigation support service provider with a secure document hosting facility that uses encrypted web-enabled

software that allows for secure and protected sharing and collaboration concerning said documents amongst only authorized counsel and that does not employ so-called "cloud computing" services. Notwithstanding the foregoing provision, Qualified Persons, as defined in the following paragraph, shall not be prohibited from exchanging electronic mails that discuss Confidential Information or from transmitting to any other Qualified Person a reasonably limited number of files containing Confidential Information through electronic mail, as attachments to an electronic mail, as long as the person transmitting the files takes reasonable steps to protect the confidentiality of the files.

- 5. **Qualified Persons.** Confidential Information may be disclosed only to the following persons (hereinafter referred to as "Qualified Persons"):
 - (a) Plaintiffs and Defendants (unless designated "outside attorneys' eyes only" per paragraph 5(g) below) and their attorneys in the above-captioned matter. Persons encompassed by the preceding sentence include the attorneys' employees (including outside copy services, organizations involved in organizing, filing, coding, converting, storing, or retrieving data or designing programs for handling data connected with this action, including the performance of such duties in relation to a computerized litigation support system, and stenographers);
 - (b) Experts retained or consulted by a party for the purpose of obtaining such expert's advice or opinion regarding any issue in this litigation, but only to the extent necessary for the expert to provide such advice or opinion, except that disclosure shall not be made to any expert if counsel for the party retaining that expert has actual knowledge that the expert has been found to have violated the terms of a protective order in any litigation or legal proceeding;

- (c) A deponent or a witness at deposition, trial or hearing, other than those who are otherwise covered by paragraph 5(b), provided there is a reasonable basis to believe that the witness will give relevant testimony regarding the Confidential Information or that disclosure is necessary to prepare the witness for the testimony. If a party wishes to show Confidential Information to such a deponent or witness before or during a deposition, hearing, or trial, the deponent or witness must be informed of this Protective Order and either sign a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" or consent under oath to abide by its provisions. This provision does not preclude the producing party from objecting to or moving to preclude disclosure to any deponent or witness, or to seek amendment of this provision in the future, if it believes it has a good faith basis for such objection or motion;
- (d) A person identified in the document as a subject of the communication, or having authored or previously received the document;
 - (e) Any person mutually agreed upon among the parties; and
 - (f) The Court or any Court personnel, including any court reporters.
- (g) Notwithstanding any other provisions in this Order, Confidential Information that has been designated HIGHLY CONFIDENTIAL/ATTORNEYS' EYES ONLY may be disclosed only to
 - (1) Outside counsel for the parties to this action, and their employees, who are actively engaged in the conduct of this lawsuit;
 - (2) A witness at any deposition in this action who is an employee of the producing party or who authored or was copied on the document;

- (3) The Court and any employee thereof; and
- (4) Experts retained or consulted by a Plaintiff for the purpose of obtaining such expert's advice or opinion regarding any issue in this litigation, but only to the extent necessary for the expert to provide such advice or opinion, except that disclosure shall not be made to any expert if counsel for the Plaintiff has actual knowledge that the expert has been found to have violated the terms of a protective order in any litigation or legal proceeding.

6. Qualified Persons Bound by Order.

- Person, other than the Court, the employees and staff of the Court, counsel of record, and the direct employees of counsel of record, and other than as set forth above with respect to those witnesses who are shown Confidential Information at a deposition, trial or hearing as identified in paragraph 5(c), shall be advised of the terms of this Order, shall be given a copy of this Order, shall agree in writing to be bound by the terms of this Order by signing a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A," and shall consent to the exercise of personal jurisdiction by this Court in any proceeding(s) to determine if the signatory violated this Order. Counsel for each party shall maintain a list of all Qualified Persons to whom they or their client(s) have provided any Confidential Information, which list shall be available for inspection by the Court.
- (b) The witness who is a Qualified Person pursuant to paragraph 5(c) but who has not signed a copy of the Non-Disclosure Agreement attached hereto as Exhibit "A" may be shown Confidential Information before or during his or her testimony, but shall

not be given a copy of the documents containing such Confidential Information to keep. The witness will review his or her transcribed testimony containing the Confidential Information for purposes of completing the errata sheet within thirty (30) days of receiving a copy of the deposition transcript from the court reporter but may not keep any portion of the transcript that discusses the Confidential Information. Once the witness has completed the errata sheet, he or she must return to the court reporter the portions of the transcript containing the Confidential Information, as well as any exhibits to that portion of the transcript. Any documents used at the deposition that contain Confidential Information (including marked exhibits) shall not be kept or maintained by the witness or his or her counsel except that Qualified Persons described in paragraph 5(b) may retain their depositions and exhibits until the completion of the Qualified Person's consultation or representation in this case, at which time he or she shall follow the procedures set forth in paragraph 6(c) below.

- (c) Any Confidential Information distributed or disclosed to a Qualified Person who is a signatory of Exhibit "A" shall be returned to the party's counsel who provided it to the Qualified Person or, with the consent of the party producing the Confidential Information, destroyed at the completion of the Qualified Person's consultation or representation in this case. Upon the request of the producing party or the Court, each such Qualified Person shall execute an affidavit stating that all such documents and copies thereof have been returned or destroyed as required.
- (d) The Court shall retain jurisdiction over any person or organization authorized, as set forth above, to receive Confidential Information as necessary to enforce the provisions of this Order.

To Challenges to Confidentiality Designation, or Notice of Intended Disclosure to Competitors. Nothing in this Order shall constitute a waiver of any party's right to object to the designation or non-designation of a particular document as a Protected Document. If a party contends that any document has been erroneously or improperly designated or not designated as Confidential Information, the document at issue shall be treated as confidential until (i) the parties reach a written agreement or (ii) this Court issues an order stating that the document is not confidential and shall not be given confidential treatment.

If a party in good faith wishes to challenge a disclosing party's designation of information or documents as confidential, or if a party in good faith desires to provide Confidential Information to a Competitor (defined as any business entity engaged in the research, development, manufacturing, or distribution of any pharmaceutical, biologic, medical device, or other FDA-regulated product), the party shall:

- (a) Notify the party that designated the information as Confidential in writing reasonably identifying the information (if Protected Documents, by identifying the production number of the documents at issue) and, in addition, if seeking to provide information or documents to a Competitor, the identity of the Competitor;
- (b) The parties shall meet and confer in an effort to reach agreement regarding the information at issue;
- (c) If, within fourteen (14) days of the objecting party's notification to the designating party, the parties cannot reach agreement on whether some or all of the information should remain designated as confidential, or should be provided to a Competitor, the party challenging the designation or seeking to provide the information to a Competitor may contact the Court for a telephonic conference in order to determine

whether the information designated as "Confidential" is not "Confidential Information" within the meaning of this Order and is not entitled to the protections of this Order. If the objecting party does not seek such a conference within thirty (30) days after expiration of the 14-day period for negotiation and the designating party has not agreed to extend the time for seeking such a conference, the information designated as "Confidential" shall be treated as "Confidential Information" within the meaning of this Order, without waiver by the objecting party to renew its objection in good faith and without unreasonable delay at a future date, following the procedure set forth above. The burden of justifying the designation shall lie with the designating party. All parties retain the right to appeal the decision of the Court.

8. <u>Authorized and Unauthorized Uses of Confidential Information.</u>

- (a) Confidential Information shall not be used for any business, competitive or other non-litigation purpose without the express written consent of counsel for the designating party, or by order of the Court. Nothing in this Protective Order shall limit any producing party's use of its own documents or shall prevent any producing party from disclosing its own Confidential Information to any person. Such disclosures shall not affect any confidential designation made pursuant to the terms of this Protective Order so long as the disclosure is made in a manner that is reasonably calculated to maintain the confidentiality of the information.
- (b) <u>Use of Confidential Information in Court.</u> If it is not feasible to redact or exclude Confidential Information from a court filing, the parties will follow Local Rules 7.2 and 116.6 (as applicable) for doing so, including any procedures adopted by this Court, for submitting to the Court under seal papers consisting of, containing, or

attaching Confidential Information. Confidential Information is not to be filed with the Court except when required in connection with motions or other matters pending before the Court. Counsel shall file under seal only those specific documents and deposition testimony designated as Confidential Information, and only those specific portions of briefs, applications, and other filings that contain verbatim Confidential Information or that set forth the substance of such Confidential Information.

- (c) <u>Security of Confidential Information.</u> Except as specifically provided in this Order, counsel shall keep all Confidential Information and Protected Documents produced to them within their exclusive possession and control, shall take all necessary and prudent measures to maintain the confidentiality of such materials and information, and shall not permit unauthorized dissemination of such materials to anyone.
- 9. <u>Subpoena by Other Courts or Agencies.</u> If another court, tribunal, quasi-judicial agency, administrative agency, or third party requests, subpoenas, or orders production of Protected Documents or Confidential Information from a party that has obtained those materials under the terms of this Order, the party shall promptly notify the producing party of the pendency of such subpoena or other process and shall comply with the terms of the order, subpoena, or other request or make such other response as provided by law. To the extent that a producing party seeks to intervene in the proceeding, quash the subpoena, or take other reasonable action to seek appropriate relief, with the cost of such opposition to the subpoena to be borne by the producing party unless otherwise agreed to by the parties, it may do so to the extent provided by law and may reach a separate agreement to that effect with the relevant party.
- 10. **Disposition of Confidential Information.** Upon the request of any party after the final conclusion of this action (including without limitation any appeals and after the time for

filing all appellate proceedings has passed), each party so requested shall return all Confidential Information to counsel for the party that produced it or destroy it (whichever is requested), or otherwise shall comply with an applicable order of the Court. The return or destruction of Confidential Information under this paragraph shall include, without limitation, all copies, and duplicates thereof. The parties shall certify, within thirty (30) days of receipt of a written request for certification, that all Confidential Information required to be returned or destroyed has been so returned or destroyed. Unless otherwise ordered by the Court, counsel may retain: (a) copies of pleadings or other papers that have been filed with the Court and that contain Confidential Information; (b) their work product; and (c) official transcripts and exhibits thereto. The terms and provisions of this Order shall continue to apply to any such materials retained by counsel.

- 11. Order Survives Termination of Action. After the termination of this action by entry of a final judgment or order of dismissal, the provisions of this Order shall continue to be binding. This Order is, and shall be deemed to be, enforceable as to the parties, their agents, and their attorneys. The terms of this Order may be enforced by filing a motion in this Court.
- 12. **Persons and Entities Bound by Order.** This Order shall be binding upon the parties, upon their attorneys, upon all signatories to Exhibit "A," and upon their successors, personal or legal representatives, subsidiaries, divisions, employees, agents, and independent contractors.
- 13. **No Waiver of Objections.** Neither this Order nor any of the procedures described above affects or constitutes a waiver of any party's right to object to the relevancy, admissibility or discoverability of any information or document or to seek an order that discovery or admissibility be had only subject to appropriate limits or restrictions, as provided by the Federal Rules of Civil Procedure, the Federal Rules of Evidence, the Local Rules of this

Court, or other applicable rules or law.

14. No Waiver of Privilege.

- (a) This Order does not affect or constitute a waiver of any party's right to withhold or redact information protected from disclosure by the attorney-client privilege, physician-patient privilege, work product doctrine, or other applicable privilege, protection, law, or regulation. Furthermore, in discovery in this lawsuit, the parties do not intend to disclose information subject to a claim of attorney-client privilege or attorney work product protection. If, nevertheless, a party (the "Disclosing Party") inadvertently discloses such privileged or work product information ("Inadvertently Disclosed Information"), pursuant to Federal Rule of Evidence 502(d), such disclosure shall not constitute or be deemed a waiver or forfeiture of any claim of attorney-client privilege or work product immunity that the Disclosing Party would otherwise be entitled to assert with respect to the Inadvertently Disclosed Information and its subject matter.
- (b) If a Disclosing Party notifies the receiving party of Inadvertently Disclosed Information, or if the receiving party discovers such an apparent inadvertent disclosure, the receiving party shall return or destroy, within ten (10) days, all copies of such information and provide a certification of counsel that all such Inadvertently Disclosed Information has been returned or destroyed. From the moment a receiving party discovers or is notified of inadvertent production, the party shall not copy, distribute, or otherwise use in any manner the disputed documents or information, and shall so instruct all persons to whom the receiving party has disseminated a copy of the documents or information.

- 15. Inadvertent Production or Disclosure of Confidential Information. In the event a party inadvertently produces Confidential Information without the required legend, the producing party shall contact the receiving party within five (5) days of the discovery of the inadvertent production, or as promptly as reasonably possible thereafter, and inform the receiving party or parties in writing of the inadvertent production and the specific material at issue. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of confidentiality, either as to specific documents and information disclosed or on the same or related subject matter. Upon receipt of such notice, the receiving party or parties shall treat the material identified in the notice as confidential until (a) the parties agree to non-confidential treatment of the subject material, or (b) the Court, on motion of any party, issues an order addressing the appropriate treatment of the subject material. Each receiving party shall further notify every person or organization that received copies of or access to the material identified in the notice that such material contains Confidential Information.
- 16. <u>Modification Permitted.</u> Nothing in this Order shall prevent any party or other person from seeking modification of this Order, or from objecting to discovery that it believes to be otherwise improper.
- 17. <u>Use of Confidential Information at Trial.</u> Nothing in this Order shall preclude a party from introducing into evidence at trial or hearing any Confidential Information or Protected Document that is admissible under the Federal Rules of Evidence, nor shall anything in this Order be construed as sealing evidence introduced at trial or hearing. At trial or evidentiary hearings, the Court may take such measures, if it should deem it appropriate, to protect the claimed confidential document or information sought to be admitted.

IT IS SO ORDERED.

Dated:	
,	United States District Judge

Through the undersigned counsel, the parties consent to entry of the Order (as it was submitted to the Court):

Dated: December 17, 2015 Respectfully submitted,

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